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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,759	09/25/2001	Philip R. Andersen	00088-008004	2138

26161 7590 11/03/2004

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,759	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24* is/are pending in the application.

4a) Of the above claim(s) *15,16,20 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,17-19,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the Election mailed May 11, 2004. Applicant's election without traverse of the Invention of Group I is acknowledged. Accordingly, claims 14, 17-19 and 22-23 are under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 17-19 and 22-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,383,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to modify the patented invention, to arrive at the invention that is presently claimed.

The patented invention is drawn to an immunoassay comprising 1) providing a Feline Immnunodeficiency Virus (FIV) envelope polypeptide, wherein the polypeptide reacts with a monoclonal antibody that recognizes FIV gp130, 2) reacting a sample with the polypeptide, and 3) detecting a reaction between the polypeptide and the sample. The only difference between the

claimed invention and the patented invention is the presence of a reacting step. That is, the claimed invention lacks a reacting step. However, it would have been obvious for one of ordinary skill in the art to provide the claimed invention with a reacting step. One skilled in the art would recognize that all immunoassays depend on a reacting step that allows an antibody to specifically bind to an analyte. Without such a reaction step, interaction between an antibody and an analyte could not occur thereby making detection of such an interaction impossible. Therefore, it would have been obvious to provide the claimed invention with a reacting step as provided in the patented invention.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' invention is drawn to a method for detecting FIV antibody comprising providing an FIV gp130 epitope, and detecting an interaction between the epitope and antibody from a sample. Applicants' invention lacks the steps of providing the sample, and incubating the sample in a reaction mixture. The state of the art has not witnessed any immunoassay that omits these steps. Moreover, it is well established that an antibody's ability to recognize a specific

epitope depends on the interaction of molecular forces during a reaction phase. Applicants' specification does not provide any guidance as to how one skilled might avoid these steps, yet detect a specific antibody/epitope interaction. Therefore, Applicants' specification fails to enable the claimed invention.

Claims 14, 17 and 18 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. As noted above, Applicants' invention is drawn to an assay for detecting FIV antibody, wherein the steps of providing and incubating a sample are omitted. However, Applicants specification fails to disclose an immunoassay that detects FIV antibody without performing these steps. A working example of such an immunoassay is also lacking. The specification therefore does not establish that Applicants' had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 17-19, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 provides that the polypeptide used to detect FIV antibody is "an isolated . . . FIV envelope polypeptide that reacts specifically with a monoclonal antibody that is specific for the envelope protein gp130 . . . ." A fair reading of the claim provides that the FIV envelope polypeptide can be *any* FIV envelope protein that specifically interacts with an anti-gp130 antibody. It is unclear how the monoclonal antibody can be "specific" for anti-gp130, yet react with any FIV envelope polypeptide. Applicants are required to particularly point out and distinctly claim the interaction that defines the FIV envelope polypeptide.

Claims 14, 17-19, 22 and 23 are also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claim 14 omits the steps of providing a sample, and incubating it with the FIV envelope polypeptide. As noted above, these steps must be performed in order to detect the polypeptide/antibody reaction.

Claim 17 is further rejected for failing to provide antecedent basis for "the reagent."

The claimed invention is free of the art. Applicants' have clearly distinguished the claimed invention from the most relevant art during the prosecution of a related case (Application Serial No. 08/852,143 now US Pat. No. 6,383,765). For example, in the response mailed January 31, 2000, Applicants distinguished their invention from Pedersen (US Pat. No. 5,037,753) noting that the specific polypeptides claimed (i.e. polypeptides that react with anti-FIV gp130 antibody) were neither taught nor suggested by the prior art (see p. 6 *et seq.*).

The prosecution of the related case also reveals that the specification is enabling insofar as it shows how to make monoclonal antibody against FIV gp130. Claims commensurate in scope with the presently claimed invention were rejected as non-enabled based on the difficulty

of isolating FIV gp130. Applicants' remarks in the response mailed January 31, 2000 persuasively demonstrated that the specification enabled production of the monoclonal FIV gp130 antibody recited in the present claims (see pp. 5-6).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel 11/1/04